Remarks/Arguments:

This amendment does not add or cancel any claims, and is provided to amend claims 1 and 3 only. However, in doing so, no new matter has been added. Upon entry of this amendment, claims 1-6 will be pending, wherein claims 1-3 are independent.

Rejections of the Claims under 35 U.S.C. 103

The Examiner has rejected claims 1, 2, 5 and 6 under 35 U.S.C. 103(a) as allegedly being unpatentable over newly cited U.S. Patent Publication No. 2002/0055711 of Lavi et al. (hereinafter Lavi) in view of newly cited U.S. Patent No. 5,976,111 of Hart (hereinafter Hart).

Specifically, the Examiner points to Lavi as disclosing a device for delivering a medicament having a housing with a top, a bottom surface adapted to contact a skin surface of a patient, a reservoir (connection), and an injection needle adapted for penetration of the skin surface and for movement through a needle aperture.

The Examiner also points to Lavi as disclosing such a device further having a safety member adapted for movement substantially perpendicular to the bottom surface of the housing, having a skin contacting portion disposed about the needle aperture and substantially covered with adhesive, and at least one shield protruding from the skin contacting portion, the safety member having a first position wherein the shield of the safety member is initially disposed within the housing and the skin contacting portion is substantially co-planar with the bottom surface of the housing, and a second position wherein the shield of the safety member is at least partially withdrawn from the housing and at least partially covers the injection needle.

The Examiner also points to Lavi as disclosing such a safety member wherein when the device is placed upon the skin surface of the patient, the skin contacting portion of the safety member is temporarily adhered to the skin surface, and when the device is removed from the skin surface, the adhesion of the safety member to the skin surface is sufficient to move the safety member from the first position to the second position

The Examiner finally points to Hart as disclosing such a device further having a reservoir disposed within the housing in fluid communication with the injection needle, such that the combination of the Lavi and Hart references purportedly renders obvious the device as recited by the Applicants in claim 1.

As noted by the Examiner, the Lavi reference does not describe a reservoir disposed with the housing of elements 210 and 220, and simply describes the provision of a drug delivery port 274 that communicates with a needle chamber 275 (see Figs. 20A-20C). The port 274 is formed through an arm 273 that extends radially from an enlarged flange portion 272 of the needle holder 270 (see paragraph 123).

Accordingly, the Examiner points to Hart as disclosing such a reservoir disposed within the housing in fluid communication with the injection needle. Specifically, the Examiner points to the syringe 10 of Hart as constituting a reservoir disposed within a housing as recited by the Applicants.

However, the Hart reference describes the provision of an auto-positioned needle guard for a syringe (see Abstract). In this, the syringe is simply provided to illustrate how the needle guard operates, and any syringe can be used to show the same or similar features. Accordingly, the Applicants assert that the provision of a syringe 10 in Hart, even if coupled with the drug delivery port 274 of Lavi, does not constitute a reservoir as recited by the Applicants, and more specifically, does not constitute a reservoir disposed within a housing with top and bottom surfaces as recited by the Applicants. That is, even where the syringe 10 is provided, it is not disposed within such a housing nor would it have been obvious to do so, but is coupled externally to a housing.

Regarding the safety member, the Examiner points to Lavi as disclosing a safety member and a rotatable door having a first position which prevents movement of the safety member, and a second position which allows movement of the safety member. Specifically, the Examiner points to the latches 237 of Lavi Figs. 18-20 as constituting such a rotatable door. The latches 237 of Lavi are configured to be pushed free by downward travel of element 270, to thereby allow the latches 237 to push the guard 231 as urged by spring 232.

However, in doing so, the latches which allegedly constitute the rotatable door, are entirely contained within the device, and behind the guard 231. In contrast, the Applicants describe a system and method wherein the rotatable door is configured to contact the skin surface. The Applicants have amended claim 1 to reflect this. This is not new matter, and is supported elsewhere in the specification (see for example, Figs. 37-41). As such, the door as recited is disposed differently that the latches 237 of Lavi.

The Examiner has also rejected claim 2 under 35 U.S.C. 103(a) as allegedly being unpatentable over Lavi in view of Hart.

In regard to independent claim 2, the Applicants recite a housing with a top, a bottom surface adapted to contact a skin surface of a patient, a reservoir, and an injection needle adapted for penetration of the skin surface and for movement through a needle aperture as in claim 1, and further recite an adhesive/skin surface activation feature wherein the adhesion (of the skin contacting portion of the safety member) to the skin surface is sufficient to activate the linear movement of a safety member. That is, in an exemplary embodiment of the present invention the safety member is linearly moved substantially perpendicular to the bottom surface of the device upon removal.

As noted above, the Hart reference describes the provision of an auto-positioned needle guard for a syringe (see Abstract). In this, the syringe is simply provided to illustrate how the needle guard operates, and any syringe can be used to show the same or similar features. Accordingly, the Applicants assert that the provision of a syringe 10 in Hart, even if coupled with the drug delivery port 274 of Lavi, does not constitute a reservoir as recited by the Applicants, and more specifically, does not constitute a reservoir disposed within a housing with top and bottom surfaces as recited by the Applicants. That is, even where the syringe 10 is provided, it is not disposed within such a housing nor would it be obvious to do so, but is coupled externally to a housing.

Further, the Applicants recite an exemplary shield that is configured to be held in place by a device activation button, wherein the shield is configured to be first released by

activation of the device activation button and then withdrawn from the housing by the adhesion to the skin surface.

In contrast, the Lavi reference describes in Figs. 3 and 36, a needle shield 631 that can be pulled from the housing through the use of an adhesion layer 617, but wherein the needle shield is prevented from movement by the needle holder. That is, as shown in Figs. 33-35, the shield element 637U is held up by contact with the shoulder 663 of the needle holder (see Fig. 33), and only when the needle holder moves down (see Fig. 34) and shoulder 663 moves down, can the shield 631 be pulled out (see Fig. 35). However, in this case, it is not the activation of the device activation button that releases the shield as recited by the Applicants, but the downward movement of the needle holder.

The Examiner has also rejected claim 3 under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 6,500,150 of Gross et al. (hereinafter Gross 1) in view of U.S. Patent No. 5,997,501 of Gross et al. (hereinafter Gross 2).

Specifically, the Examiner points to Gross 1 as disclosing a device for delivering a medicament having a housing with a top, a bottom surface adapted to contact a skin surface of a patient, and an injection needle adapted for penetration of the skin surface and for movement through a needle aperture.

The Examiner also points to Gross 1 as disclosing such a device further having a reservoir disposed within the housing in fluid communication with the injection needle, and a safety member adapted for rotational movement along an arcuate path relative to the bottom surface of the housing, and having a skin contacting portion disposed about the needle aperture and substantially covered with adhesive, and a pivot, such that the safety member has a first position wherein the safety member is substantially co-planar with the bottom surface of the housing, and a second position wherein the safety member is rotated about the pivot and the safety member at least partially covers the injection needle.

The Examiner points to Gross 1 as disclosing such a safety member wherein when the device is placed upon the skin surface of the patient, the skin contacting portion of the safety member is temporarily adhered to the skin surface and when the device is removed from the

skin surface, the adhesion of the safety member to the skin surface is sufficient to rotate the safety member about the pivot from the first position to the second position.

The Examiner points to Gross 2 as disclosing such a safety member having a securing means while in the first position such that the safety member is secured against and substantially co-planar with the bottom surface of the housing in the first position, such as in a pre-use position.

In the Applicants' disclosure, a securing means can be achieved through the use of, for example, the door 790 and door latch 791 of Fig. 39 (see also paragraph 319), and the lock arm 1034 of Fig. 123 (see also paragraph 342). For example, the device can be positioned against a skin surface, and movement of the push button releases the latch or lock arm. However, as the device is adhesively positioned against a user's skin, no movement of the safety member is allowed, but is free to move upon removal of the device. In doing so, the Applicants recite a system and method wherein the safety member has a securing means while in the first position such that the safety member is secured against and substantially co-planar with the bottom surface of the housing, such as in a pre-use position.

The Gross 2 reference describes a protective displaceable cover 303 which can be coated with an adhesive to be pulled by a skin contact surface to an extended position. A resistance to such movement is provided by the rounded projections at ends thereof and which are displaced in notches 305 and 306 (see Figs. 15 and 16, and col. 13, lines 25-35).

However, there is no disclosure in Gross 2 that the projections are released from the notches 305 or 306 by activation of the device. That is, the notches and detents of Gross 2 are simply provided to hold a retracted or extended position against minimal resistance. In contrast, the Applicants recite a system and method wherein activation of the device releases the securing means. The Applicants have amended independent claim 3 to recite this distinction. Specifically, the Applicants have amended independent claim 3 to recite that the securing means is released *by activation of the device* such that when the device is removed from said skin surface, adhesion of the safety member to the skin surface is permitted to rotate the safety member.

As noted above, an exemplary securing means can be achieved through the use of the door 790 and door latch 791 of Applicants' Fig. 39 and the lock arm 1034 of Applicants' Fig. 123. The device can be positioned against a skin surface, and movement of the push button releases the latch or lock arm, and the door is free to move upon removal of the device. In doing so, the Applicants recite a system and method wherein the safety member has a securing means while in the first position such that the safety member is secured against and substantially co-planar with the bottom surface of the housing, such as in a pre-use position, which is not described by the detents of Gross 2.

Accordingly, for at least these reasons, the Applicants assert that the Lavi, Hart, Gross 1 and Gross 2 references separately or in combination, do not disclose or reasonably suggest each element as recited in independent claims 1, 2 and 3, and respectfully request the withdrawal of the rejection under 35 U.S.C. 103(a). Dependent claims 4, 5 and 6 which are dependent from claims 1, 2 and 3, are allowable for at least these reasons.

Conclusion

In view of the above, it is believed that the application is in condition for allowance and notice to this effect is respectfully requested. Should the Examiner have any questions, the Examiner is invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

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